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10/565,356	12/04/2007	Robert M. Pricone	08-508-WO-US	5581

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EXAMINER	
LUK, EMMANUEL S	

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1791	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/565,356	PRICONE, ROBERT M.	
	Examiner	Art Unit	
	EMMANUEL S. LUK	1791	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *36-42* is/are allowed.

6)☒ Claim(s) *1,6-14,19-35 and 43* is/are rejected.

7)☒ Claim(s) *2-5 and 15-18* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/20/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-43 are pending.

2. Claims 1-18 and 24 have invoked means plus function pursuant to 35 U.S.C. 112, sixth paragraph. Where means plus function language is used to define the characteristics of a machine or manufacture invention, claim limitations must be interpreted to read on only the structures or materials disclosed in the specification and "equivalents thereof." (Two en banc decisions of the Federal Circuit have made clear that the Office is to interpret means plus function language according to 35 U.S.C. 112, sixth paragraph. In the first, In re Donaldson, 16 F.3d 1189, 1193, 29 USPQ2d 1845, 1848 (Fed. Cir. 1994), the court held:

The plain and unambiguous meaning of paragraph six is that one construing means-plus-function language in a claim must look to the specification and interpret that language in light of the corresponding structure, material, or acts described therein, and equivalents thereof, to the extent that the specification provides such disclosure.

Claim 1 fails to invoke means plus function for “exhaust means” as it is an improper language to invoke 112, sixth paragraph.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 15-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 16 and 17 recite the limitation "said gasket"

in line 1 of both claims. Claims 15 and 18 recites the limitation "said gas permeable membrane" in line 1. There is insufficient antecedent basis for this limitation in the claim. Examiner for expediency sake will assume claims 15 is dependent upon claim 3 and 16-18 are dependent upon claim 15. This reflects a similar grouping as per claims 11-14.

5. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim fails to properly invoke means plus function language and instead states "exhaust means" which does point out and distinctly claim the subject matter.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 9, and 11-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Rieker (5945196).

Rieker teaches the formation of a film with protuberances by having the film placed upon a molding surface (screen, 30), the screen being tapered towards the end, see Figures 9-11, the tapered end of the product having apertures 168 at the protuberance 165. A vacuum chamber 68 forms a pressure differential that causes the

film 62 to be pulled through the first openings 47 of the film into the perforations 42 and through the second openings 48, the pressure differential sufficient to form three dimensional protuberances 72 on the bottom surface 66 of the film 62 (Col. 7, line 61 to Col. 8, line 6) and the pressure differential can be regulated to form apertures as the protuberances rupture in the film (Col. 8, lines 17-24).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 6-8, 10 and 19-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rieker (5945196) in view of in view of Montierth (4670205).

Rieker teaches the formation of a film with protuberances by having the film placed upon a molding surface (screen, 30), the screen being tapered towards the end, see Figures 9-11, the tapered end of the product having apertures 168 at the

protuberance 165. A vacuum chamber 68 forms a pressure differential that causes the film 62 to be pulled through the first openings 47 of the film into the perforations 42 and through the second openings 48, the pressure differential sufficient to form three dimensional protuberances 72 on the bottom surface 66 of the film 62 (Col. 7, line 61 to Col. 8, line 6) and the pressure differential can be regulated to form apertures as the protuberances rupture in the film (Col. 8, lines 17-24). The film worked upon can be any flexible film or sheets, see Col. 10, lines 47-61. The width of the perforations can range from about 7 mils to about 11 mils, see Col. 8, lines 1-9, thereby forming microprotuberances.

Rieker fails to teach the mold construction, pressure, and height.

In regards to the inert gas, air used by the vacuum is considered inert to the thermoplastic film.

In regards to the mold construction, the use of polymeric construction and metallic construction for at least a portion of the mold assembly would have been obvious since both metal and polymeric materials are well known in use for constructing molding assemblies in the art and

In regards the pressure used, Rieker teaches controlling the pressure such that the pressure can either rupture or not rupture the film as desired along with causing the material to form within the cavity. Depending upon the material used, it would have been obvious for one of ordinary skill in the art to modify Rieker with the pressure accordingly for a controlled results upon the product worked upon (in this case the film).

In regards to the cavity height, Rieker teaches forming three dimensional films with microprotuberances including details of the width being 7 to 11 mils. This is about 177.8 microns, this is close to the scale of the claimed cavity array with the height of 160 microns and base diameter of 50 microns. Both are on the micron range for forming upon the product and it would have been obvious for one of ordinary skill in the art to modify Rieker with a change is size for forming the desired product size as Rieker already teaches formation of products on the same range.

11. Claim 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rieker in view of as applied to claim 19 above, and further in view of Jarvenkyla.

Rieker does teach the length of time for the film to be under pressure differential such that the shape 'sets' in the film 62, (Col. 8, lines 14-17).

Rieker fails to teach curing the material.

Jarvenkyla teaches the material fed under flowing medium and being chilled such that the material is cured. Jarvenkyla also teaches the use of gas and liquid flowing such that the shape of the

12. Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rieker (5945196) in view of Bosler (2003/0080475) and Huang (2005/0173845).

Rieker teaches the claimed apparatus as shown above. Rieker fails to teach the first and second belt means.

Bosler teaches first and second belt means 15, 17, with vacuum manifolds 28 that aids in drawing out the material, the belts having a plurality of shaping surfaces (teeth, see [0008]).

Huang teaches a continuous forming material for forming shaped surface utilizing a flexible mold on a belt (see Figure 7) with recesses, with heated air from a heater 8, and the vacuum device 9 to draw the material into the recess which can rupture the film to form apertures at the screen holes (see [0025]).

It would have been obvious for one of ordinary skill in the art to modify Rieker with the belt means as taught by Bosler thereby allowing for continuous production of the product and with the belt means with heater as taught by Huang to ensure the material is softened during operation.

Allowable Subject Matter

13. Claims 2-5, and 15-18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 2-5 and 15-18 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

14. Claims 36-42 are allowed.

15. The following is a statement of reasons for the indication of allowable subject matter: The prior art of record fails to teach the apparatus with the bore for forming microneedles and the fluid exhausted through the cavity and bore, the mold assembly further having an upper and lower manifolds separated by a fluid tight gasket. The closest prior art, Rieker, fails to teach the additional gasket feature that separates the upper and lower manifold.

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Raley	4252516
Mullane	4741877
Bacher	5073237
Gore	5252279
Jarvis	5383512
Eigen	5447679
Bacher	5543108
Sherman	6451240

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to EMMANUEL S. LUK whose telephone number is (571)272-1134. The examiner can normally be reached on Monday-Fridays from 9 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yogendra N. Gupta can be reached on (571) 272-1316. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Yogendra N Gupta/
Supervisory Patent Examiner, Art Unit 1791

EL